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3368/1D888-US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Charles E. ROGLER et al.

Serial No.: 09/344,189

Art Unit: 1632

Filed: June 24, 1999

Examiner: P. Paras, Jr.

For: **CHRONIC HEPATITIS VIRUS INFECTION AND CLONAL HEPATOCELLULAR CARCINOMA IN MOUSE REPOPULATED LIVERS**

DECLARATION OF CHARLES E. ROGLER
UNDER 37 C.F.R. §1.131

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

The undersigned declares and says that:

1. I am a citizen of the United States and I am more than 21 years old.
2. I am a co-inventor of this application and I make this declaration in support of the application.
3. I have read and am familiar with the Office Action mailed in this application

on June 7, 2001. I have also read and am familiar with Vierling, U.S. Patent No. 6,034,927 ("Vierling") which in combination with other references under 35 U.S.C. §103 has been relied upon by the Examiner to reject claims 1-36 of this application.

4. The invention recited in the present claims was completed before the September 26, 1997 filing date of the Vierling patent. That is, Joerg Petersen and I and those working under our supervision and control, designed and completed experiments demonstrating such completion in the United States prior to September 26, 1997.

5. As evidence of the preceding paragraphs, I refer to a paper by Petersen et al. (Proc. Natl. Acad. Sci. USA, 95:310-315, 1998; hereinafter, "Petersen"), of which I am a co-author and which is already of record in the file of the subject application. Petersen was received for review on August 22, 1997. This is stated in Petersen at the top of page 310. All experiments described in Petersen were performed before August 22, 1997. Petersen describes the present invention in detail.

6. Petersen includes a description and discussion of experiments showing development of a mouse model to investigate host and viral mechanisms determining hepadnaviral persistence and hepatocarcinogenesis. (Abstract, lines 1-3). Petersen describes methods for generating immunetolerant, uPA/RAG-2 mice, isolating mammalian (woodchuck) hepatocytes, and transplantation of the isolated hepatocytes into immunetolerant mice by intrasplenic injection (p. 311, Methods). Petersen also shows results of experiments demonstrating successful transplantation of xenogenic hepatocytes into degenerated mouse liver; infection of the transplanted hepatocytes with a compatible hepatitis virus; and persistence of viral infection (pp. 311-312, Results). Petersen also demonstrates the presence of precancerous and malignant phenotypes of the transplanted infected hepatocytes (pp. 313-314). Petersen also discloses that the mouse model offers the chance

to study mechanisms of viral persistence in the absence of B and T cell mediated immune responses, viral replication, antiviral compounds and hepatocarcinogenesis (pp. 314-315, Discussion).

7. Additionally, Figures 1-6 of Petersen are identical to Figures 1-6 of the present application.

8. All the experiments in Petersen were conducted in the United States.

9. In summary, Joerg Petersen and I conceived and diligently reduced the present invention to practice prior to September 26, 1997.

10. This Declaration is submitted for the sole purpose of establishing a date of conception and reduction to practice for the present invention prior to September 26, 1997.

11. This present Declaration does not represent a surrender of the right to establish that the present invention was conceived and reduced to practice prior to September 26, 1997. The right to establish dates of conception and reduction to practice for the invention that are prior to September 26, 1997 is specifically reserved.

12. I further declare that all statements herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the present application or any patent issuing thereon.

Dated: 9/7/01

Signed: 

Charles E. Rogler

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DECLARATION OF CHARLES E. ROGLER UNDER 37 C.F.R. §1.131

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